In Re Application of:	Kolter et al.	Docket No.:	51284
Serial No.:	09/811,546	Confirmation No.:	9100
Filing Date:	3/20/2001	Examiner:	SILVERMAN, ERIC E
Customer No.:	26474	Art Unit:	1615

For: Solid oral dosage forms with delayed release of active ingredient and high mechanical stability

Honorable Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Applicants request review of the final rejection in the above-identified application. No amendments are being filed with this request. This request is being filed with a notice of appeal. The review is requested for the reasons stated on the attached sheets.

Please charge any shortage in fees due in connection with the filing of this paper, including Extension of Time fees, to Deposit Account 14.1437. Please credit any excess fees to such account.

Status of Claims: Claims 1, 3 – 19 and 21 – 27 are currently pending, Claims 2 and 20 are canceled,Claims 25 and 26 have been withdrawn from consideration by the examiner, and Claims 1, 3 – 19 and 21 – 24 stand rejected.

Respectfully submitted,
NOVAK DRUCE DELUCA & QUIGG, LLP

Michael P. Byrne

Michael P. Byrne
Registration No.: 54,015

1300 Eye St. N.W.
Suite 1000 West
Washington, D.C. 20005
Phone: (202) 659-0100
Fax: (202) 659-0105

Remarks

Regarding the Rejection under 35 U.S.C. §103:

Claims 1, 3 – 19, and 21 – 24 stand rejected under 35 U.S.C. §103(a) over Kolter et al. (US 6,066,334) in view of Ortega (US 4,837,032). This rejection is based upon clear legal and factual deficieneies. Little, if any, interpretation of the claims or the references is required to conclude that the rejection should be withdrawn.

Kolter et al. is directed to instant release or quick release preparations, and no apparent reason has been shown to modify Kolter et al. to arrive at the delayed release preparation of the present invention. lnstead, the examiner has asserted that no patentable weight is given to the phrase "dosage form with delayed release," merely because the phrase is in the preamble to the claim. In the Advisory action mailed June 11, 2007, the examiner stated, "[w]hile Applicant is correct that the preamble may be afforded patentable weight in some circumstances, in this case, the claims do not require the preamble to breath[e] life and … meaning to them."

As was pointed out in the reply to the final Office action mailed February 26, 2007, "[t]he determination of whether a preamble limits a claim is made on a case-by-case basis in light of the facts in each case; there is no litmus test defining when a preamble limits the scope of a claim."[1] However, "clear reliance on the preamble during prosecution to distinguish the claimed invention from the prior art transforms the preamble into a claim limitation because such reliance indicates use of the preamble to define, in part, the claimed invention…."[2] Applicants have clearly relied on the preamble during prosecution to distinguish from the cited references, thus the examiner's refusal to "afford patentable weight" to the preamble is in error.

Moreover, the preamble of claim 1, "An oral dosage form with delayed release of active ingredient …" when read in the context of the entire claim clearly recites a limitation of the claim. Thus, even if applicants had not clearly relied on the preamble during prosecution, the claim preamble should be given patentable weight. "If the claim

[1] MPEP § 2111.02, citing Catalina Mktg. Int'l v. Coolsavings.com, Inc., 289 F.3d 801, 808, 62 USPQ2d 1781, 1785 (Fed. Cir. 2002).
[2] Catalina Mktg. Int'l v. Coolsavings.com, Inc., 289 F.3d at 808-09, 62 USPQ2d at 1785.

preamble, when read in the context of the entire claim, recites limitations of the claim, or, if the claim preamble is 'necessary to give life, meaning, and vitality' to the claim, then the claim preamble should be construed as if in the balance of the claim."[3] The examiner has erred in cursorily characterizing this limitation as a "recitation of intended use," because "[t]he determination of whether preamble recitations are structural limitations or mere statements of purpose or use 'can be resolved only on review of the entirety of the [record] to gain an understanding of what the inventors actually invented and intended to encompass by the claim.'"[4]

The examiner's proposed combination does not teach all of the claim limitations, because it does not teach an oral dosage form with delayed release of active ingredient. For this reason, the examiner has failed to establish a *prima facie* case of obviousness. "To establish a *prima facie* case of obviousness … the prior art reference (or references when combined) must teach or suggest all the claim limitations."[5] The present rejection is in error and should be withdrawn.

Moreover, since the Kolter et al. reference is directed to:

> [a] solid, rapid release, pharmaceutically active composition, from which the active ingredients are released within a time of from 0.1 to 1 hour, as measured in simulated gastric acid[,][6]

it should be clear that in order to start from the Kolter et al. reference and arrive at the present invention which is directed to:

> [a]n oral dosage form with delayed release … comprising from 20 to 80% … of a formulated mixture of polyvinyl acetate and polyvinylpyrrolidone…wherein the ratio of polyvinyl acetate to polyvinylpyrrolidone is from 6:4 to 9:1 and said formulated mixture of polyvinyl acetate and polyvinylpyrrolidone facilitates said delayed release[,]

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[3] *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165-66 (Fed. Cir. 1999).
[4] MPEP § 2111.02, citing Corning Glass Works, 868 F.2d at 1257, 9 USPQ2d at 1966.
[5] MPEP §2143.
[6] Claim 1 of US 6,066,334.

a change in the principle of operation of the Kolter et al. reference would be required. To start from the Kolter et al. reference and arrive at the present invention, a skilled artisan would need change the principle of operation of the Kolter et al. reference by changing from a rapid release composition to a dosage form with delayed release of active ingredient. It is well-settled that "[i]f the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims prima facie obvious."[7] Thus, a *prima facie* case of obviousness has not been established, and it seems unlikely that a *prima facie* case of obviousness could be established using Kolter et al. as the primary reference.

Applicants note that the examiner has stated, "Kolter teaches a range of release times"[8] and that Ortega teaches "how to optimize the release profile."[9] The examiner's argument is not well-taken, because the release times mentioned by Kolter are all immediate release times within a very narrow range. Ortega provides no teaching, suggestion, motivation or apparent reason to change the principle of operation of the Kolter et al. reference by changing from a rapid release composition to a dosage form with delayed release of active ingredient.

Finally, the examiner is directed to page 3, lines 17 – 21 of the specification, which states:

> [t]he formulated mixture of polyvinyl acetate and polyvinylpyrolidone is, because it is an intimate mixture of a lipophilic with a hydrophilic polymer, more suitable for release slowing than are the abovementioned substances. Combinations of this type are described in US patent 5,490,990.

By formulating PVP and PVAc together prior to admixing the formulated mixture with the other components an intimate mixture of the two copolymers is formed. Of course, the distinctive release patterns of the present invention are due to the formulation of the dosage forms plus the choice of amounts used in the overall mixture not only to the presenee of the formulated mixture of polyvinyl acetate (PVAc) and

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[7] MPEP §2143.01, citing In re Ratti, 270 F.2d 810, 123 USPQ 349 (CCPA 1959)
[8] Page 4, line 5 of the present Office action.
[9] Page 4, line 6 of the present Office action.

polyvinylpyrrolidone (PVP).

In comparison, Ortega discloses granulating PVP and active ingredient in the presence of an organic solvent and subsequently mixing the dried granules with PVAc and a lubricant mixture. Neither Ortega nor Kolter et al. disclose a formulated mixture of PVP and PVAc as required by the present claims.

Thus, the examiner's argument that "Ortega specifically teaches changing the release rate or profile by altering the amount of binder[,]"[10] ignores an important feature of the claimed invention, i.e., the requirement of a formulated mixture of polyvinylacetate and polyvinylpyrrolidone. The examiner's argument also seems to demonstrate a misunderstanding of the claimed technology. As mentioned in the reply to the Office action of July 03, 2006, combining the disclosures of the Kolter et al. reference and the Ortega reference, and modifying the amount of a randomly chosen binder, does not result in a change of the principle of operation of the Kolter et al. reference so as to impart delayed release properties. Thus, even when combined, the references fail to teach or suggest all of the claim limitations. Again, "[t]o establish a *prima facie* case of obviousness ... the prior art reference (or references when combined) must teach or suggest all the claim limitations."[11] The examiner has not established a *prima facie* case of obviousness. The present rejection is in error and should be withdrawn. Favorable action is solicited.

In conclusion, the rejection is based upon clear legal and factual deficiencies. Little, if any, interpretation of the claims or the references is required to conclude that the rejections should be withdrawn. Favorable action is respectfully requested.

[10] Page 4, lines 13 – 14 of the present Office action.
[11] MPEP §2143.